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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,108	02/10/2004	Charles R. Ashby JR.	BSA 04-09	2666

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EXAMINER	
RAE, CHARLESWORTH E	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,108	ASHBY, CHARLES R.	
	Examiner	Art Unit	
	Charleswort Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 8/4/06, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Status of the Claims

Claims 9 and 15 are pending in this application and are the subject of this Office action.

Applicant's amendment of 8/4/06, canceling claim 10 and amending claims 9 and 15, is acknowledged and made of record. It is noted that Applicant's Listing of Claims erroneously state to amend claims 9 and 11; however, claim 11 is cancelled. Thus, only claims 9 and 15 are pending.

Objection to the Specification - Abstract

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computed tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is need for consulting the full patent text for details. In the instant case, the

abstract recites the term "Novel." The use of this legal phraseology should be avoided. Applicant's cooperation is requested in correcting this deficiency in the abstract.

Objection to the Specification

The use of the trademarks on pages 4, 5, 10, and 11 of the specification has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim rejections – 35 USC 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 USC 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 15 recite the terms "GABA" and "GABAergic," but fail to state the full meaning of the terms at the first occurrence the terms are recited in the claim set. These limitations are vague and indefinite because it is not clear what "GABA" and "GABAergic" mean. It is suggested that this specific rejection may be overcome by either replacing the terms "GABA" and "GABAergic" with the full names or, alternatively,

amend the claims by inserting the full names in parenthesis at the first occurrence of the terms in the claim.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9 and 15 are rejected under 103(a) for being unpatentable over Seiler et al. (U.S. Patent 4,540,582) in view of Evans et al. (US Patent Application Publication 2002/0048612A1).

The instant invention is directed towards a composition consisting essentially of gamma vinyl GABA and vitamin B6, wherein the B6 is in an amount of about 50mg/day

to about 100mg/day (i.e. claim 9). Claim 15 recites the additional limitation "wherein the gamma vinyl GABA is in an amount of about 100mg/kg to about 300mg/kg.

Seiler et al. (4,540,582) teach a method for controlling seizures in a patient in need thereof comprising administering to said patient in combination an effective amount of gamma-vinyl GABA, or a pharmaceutically acceptable salt thereof, and an effective amount of glycine, sarcosine (N-methylglycine), or N,N-dimethyl-glycine, or a C1-C8 alkyl ester thereof, or a pharmaceutically acceptable salt thereof. (column 2, lines 1-10). Seiler et al. teach that the term "seizures" includes both convulsive and non-convulsive seizures associated with, for example, epiplesy, trauma, drug withdrawal (e.g. alcohol withdrawal, barbiturate withdrawal, and benzodiazepine withdrawal), tetanus, metabolic disease, elevated body temperature, drug induction (e.g.theophylline), and porphyria (column 2, lines 11-17). Seiler et al. teach doses of GVG ranging from 50 mg/kg (column 7 to 8, Table 1) to 750 mg/kg (column 6, lines 21-45). However, Seller et al. do not teach compositions consisting essentially of gamma vinyl GABA and vitamin B6.

Evans et al. teach GABA substrate compositions containing one or more alkali metal or alkaline earth metal salts of n-butyric acid in a pharmaceutically acceptable carrier (page 1, paragraph 0012). Evans et al. teach compositions containing one or more butyrates and one or more optional ingredients such as antioxidants, antidepressants, memory promoters/enhances, various vitamins, nutritional and herbal supplement (page 1, paragraph 0014). Evans et al. disclose that absorption of these compounds is believed to promote transfiguration into GABA, to raise the level of GABA

in the brain. Evans et al. also teach that one or more butyrates are formulated with promoters, including pyridoxine 5-phosphate, to enhance transformation to GABA (page 2, paragraph 0020, lines 1-3). Evans et al. disclose an exemplary composition comprising vitamin B6, L-glutamine, magnesium butyrate, and other ingredients; the amount per dosage of vitamin B6 is listed as 0-40 mg (Table 1, page 3). The limitation recited in claim 9 "wherein the vitamin B6 is in an amount of about 50 mg/day to about 100 mg/day" when given its broadest reasonable possible interpretation encompass doses less than 50 mg/day, including doses of 40 mg/day. Evans et al. also teach that the suggested dosage ranges are not intended to limit the scope of the invention in any way (page 3, paragraph 0038, lines 9-10). Thus, the daily dose range of vitamin B6 as claimed in the instant application overlaps with the dose of vitamin B6 taught by Evans et al. Evans et al. also teach that the compositions are based on the butyric acid moiety and may comprise analogs, homologs, etc. (page 3, paragraph 0041, lines 1-3). Evans et al. disclose that analogs of butyric acid include both structural and functional analogs; functional analogs are those compounds which are functionally related to the activity of butyric acid, while structural analogs are those compounds which are related to butyric acid in arrangement or number of carbon atoms (page 4, paragraph 0041, lines 1-6). The term "consisting essentially of" recited in claim 9 is reasonably consistent with the teaching of Evans et al. i.e. compositions containing one or more butyrates and one or more optional ingredients such as antioxidants, antidepressants, memory promoters/enhances, various vitamins, nutritional and herbal supplement (page 1, paragraph 0014). Based on the teaching of Evans et al. that one or more butyrates

when formulated with promoters, including pyridoxine 5-phosphate, enhance transformation to GABA (page 2, paragraph 0020, lines 1-3), someone of skill in the art would have been motivated at the time of the instant invention to combine the teachings of Seller et al., in view of Evans et al. to create a pharmaceutical composition comprising gamma vinyl GABA and vitamin B6.

Baxter et al. is being added as a secondary reference to show the state of the art only (Baxter P. Epidemiology of pyridoxine dependent and pyridoxine responsive seizures in the UK. Arch Dis Child 1991; 81:431-433, **electronic copy**, pages 1-7; also see introduction, lines 1-2). Baxter et al. teach that early onset seizures are responsive to pyridoxine (introduction). Baxter et al. also teach that the usual oral dose of pyridoxine is 30 mg/kg/day to a maximum dose of 1000 mg/kg/day) (electronic page 3, lines 2-3).

Thus, based on the motivation provided by Evans et al. for compositions of one butyrate and a vitamin, coupled with the knowledge in the art of the antiseizure properties of pyridoxine and gamma vinyl GABA, someone of skill in the art would have found it obvious at the time the instant invention was made to create the instant invention with a reasonable expectation of success in view of the teachings of Seiler et al. in view of Evans et al.

With respect to applicant's arguments in response to the Office action of 5/18/06, applicant assert's that there is no disclosure in Evans et al. of a composition containing vitamin GVG and vitamin B6 and that the composition in Evans et al. disclose the dosage of vitamin B6 to be 30mg/day. Applicant also assert's that the amended claim 9

overcomes this rejection because Evans et al. does not teach a composition containing GVG and vitamin B6, wherein the amount of vitamin B6 is about 50 to 100mg/day. Applicant's arguments are not deemed to be persuasive for the above reasons.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 8 a.m. to 4:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

16 February 2007
CER

Ardin H. Marschel 2/19/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER